

Claim 24 has been added. Support for this claim is found in the specification at, for example, Examples 1-4; and in original claim 1.

Claim 25 has been added. Support for this claim is found in the specification at, for example, page 11, line 31 - page 12, line 3 and in original claim 1.

Denial of Benefit to Priority Applications

In the Office Action, the Examiner asserts "that no priority documents are provided with this application which has been indicated in our first Office Action." (Paper 8 at 3). The Examiner is wrong. Had the Examiner looked at page 2 of the transmittal letter, it would have been clear that priority was claimed to EP 98122412.4 and EP 00119337.6. (p. 2, ¶7). A copy of the transmittal letter is attached as Exhibit 2. Moreover, an inspection of the transmittal letter would have also informed the Examiner that a certified copy of EP 981122412.4 was forwarded with the transmittal papers. (*Id.* at ¶7a). Exhibit 3 is a date-stamped post card confirming receipt by the PTO of the application papers *including* the certified copy of EP 981122412.4. This post card is *prima facie* evidence of receipt in the PTO of the certified copy of EP 981122412.4. *See* MPEP 503.

The record is also clear that a Submission of Priority Document Under 35 USC §119 was filed on December 7, 1999. Accompanying this Submission was a certified copy of EP 00119337.6. Exhibit 4 is a date-stamped post card confirming receipt by the PTO of the certified copy of EP 00119337.6. This post card also is *prima facie* evidence of receipt in the PTO of the certified copy of EP 00119337.6. *Id.*

As a courtesy to the Examiner, attached as Exhibits 5 and 6 are copy sets of the certified copies of EP 98122412.4 and EP 00119337.6. In view of the foregoing, there can be no

question that the statutory predicates to claiming benefit to the two EP applications have been more than met in this case.

Indefiniteness Rejection

Claim 8 was rejected (presumably under 35 USC §112, second paragraph.) (Paper No. 8 at 4). In making the rejection, the Examiner contended only that “[c]laim 8 is improperly dependent on claim 1. *Claim 8* does not further limit *claim 8*.” (*Id.*).

Claim 8 has been amended to place it in independent form. Accordingly, the rejection has been rendered moot and should be withdrawn.

Anticipation Rejections

It appears that the rejection under 35 USC §102(b) over Miettinen has been “maintained.” (Paper No. 8 at 2). The purported rejection, however, states only that:

Claims rejected as being anticipated by WO 92/19640 lines 4-6, page 5; lines 8-37, page 6; *Claims 1, 5, and 6* is maintained

Claims are amended but *claims 1-7* are still considered anticipated, see lines 20-24, page 10; lines 22-30 page 9. (*Id.*).

The rejection provides nothing more.

Miettinen disclose a β -sitostanol fatty acid ester or fatty acid ester mixture that lowers serum cholesterol levels and processes for producing the ester or ester mixture. *See Abstract.* Miettinen further disclose:

In accordance with the invention, the β -sitostanol mixture, which contains campestanol approx. 6%, is esterified with *different* fatty acid ester mixtures by a commonly known chemical interesterification technique. A *methyl ester* mixture of the fatty

acids of *any* vegetable oil can be used in the reaction. One example is a mixture of rapeseed oil and methyl ester, but *any* fatty acids which contain approx. 2-22 carbon atoms are useable. (Page 6, lines 24-34).

The process used to produce the "stanol fatty acid esters" in Miettinen is disclosed to include "no other substances other than free stanol, a fatty acid ester or a fatty acid mixture, and a catalyst." (Page 6, line 35 - Page 7, line 2).

Claim 1, as amended, recites a phytosterol ester compound produced from a reaction of a phytosterol with eicosapentaenoic acid or docosahexaenoic acid. The rejection identifies no disclosure in Miettinen of "a reaction of phytosterol with eicosapentaenoic acid or docosahexaenoic acid" as recited in claim 1.

Moreover, claims 1 as amended and claim 24 now recite that the phytosterol ester compound is "a liquid at temperatures from about -20°C to about 20°C." The rejection identifies nothing in Miettinen that discloses or suggests this characteristic of the claimed compound.

In short, Miettinen does not disclose each and every element of the claimed invention. For the foregoing reasons, the rejection has been rendered moot and should be withdrawn.

Claims 1-4 were rejected under 35 USC §102(b) as anticipated by Shimada *et al.*, *JAOCS*, 76(6):713-716 (1999) ("Shimada"), in a rejection apparently copied from the last Office Action. (Paper No. 8 at 5). In making the rejection, the Examiner asserted:

See Table 3 on page 716 where esterification of sitosterol (which is phytosterol) are disclosed. Fatty acid is the same as has [sic] claimed in amended claim 1, *i.e.* docosahexaenoic acid and eicosapentaenoic acid.

(*Id.*).

We fully responded to this rejection in our last Response (dated February 28, 2001). However, the Examiner has neither taken note of the argument, nor answered it in any way. But this was the Examiner's burden. "Where the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicant's argument and answer the substance of it." MPEP § 707.07(c). Because our argument remains fully responsive to the rejection and has not been answered by the Examiner, the rejection must fail. For the Examiner's convenience, however, our unrebutted position with respect to Shimada is set forth below.

For the reasons presented below, the rejection, respectfully is traversed.

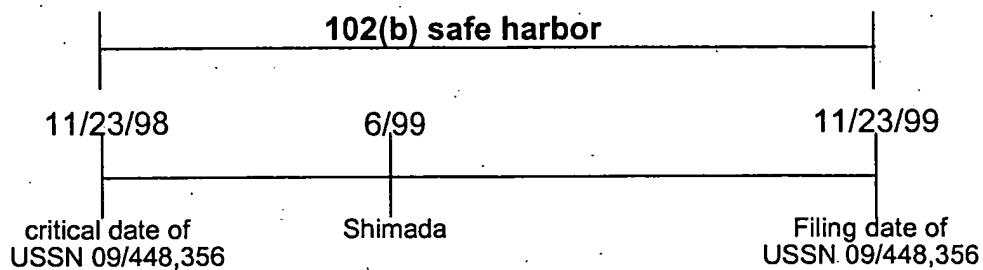
Shimada discloses the synthesis of steryl esters of PUFA with a lipase from *Pseudomonas* sp. (Page 712, Col. 2). To show that the disclosed enzymatic method is effective for the synthesis of steryl esters of PUFA, Shimada further disclosed in Table 3 the esterification of cholesterol, cholestanol, and sitosterol with a number of fatty acids, including docosahexaenoic acid and eicosapentaenoic acid. (Page 715, Col. 2 and Table 3).

Under 35 USC §102(b), "a person shall be entitled to a patent unless the invention was ... described in a printed publication in this or a foreign country ... ***more than one year prior to the date of the application*** for patent in the United States." Thus, under the statute, there is a one year grace period or "safe harbor" from the effective U.S. filing date of the subject application in which certain activities (e.g., publications) will not constitute anticipation. *See* MPEP 2133 at 2100-75.

The publication information in Shimada is set forth as follows: "Paper no. J9028 in *JAOCs* 76, 713-716 (*June 1999*)" (See the first line under the Abstract) and "[Received September 24, 1998; accepted February 16, 1999]" (See Page 716, Col. 2, last line). The present

application, however, was filed in the U.S. on *November 23, 1999*, and was accorded that day as the date of filing. As Time Line-1 below shows, Shimada on its face, does not identify a date of publication more than one year prior to the U.S. filing date of the present application.

Time Line-1



Accordingly, Shimada is not prior art to the present claims under §102(b), and cannot be used to reject claims 1-4 in the manner set forth in the Office Action. *We note for the Examiner's benefit, that regardless of the priority issue, simply based on the U.S. filing date of the present application, Shimada is not prior art under §102(b).* Accordingly withdrawal of the rejection, respectfully is requested.

Obviousness Rejection

Claims 1-6 and 8 were rejected under 35 USC §103 as unpatentable over Novak WO 00/04887 (International Application No. PCT/CA99/00655) ("Novak"). (Paper No. 8 at 5).

Apparently responding to our prior argument concerning this rejection, the Examiner asserted that “[a]pplicant’s argue that due to priority the 102 rejections should be withdrawn. Note, that no priority documents are provided with this application which has been indicated in our first office action. All the rejections are maintained for the reasons set forth in our previous and other office actions.” (Paper 8 at 3). As discussed above, priority has been

claimed under 35 USC § 119 to two European Patent Applications, EP 98122412.4 and EP 99119337.6. (Exhibits 3 and 5, respectively). Certified copies of each have been provided to the Office. Date-stamped postcard receipts for each document are attached. (See Exhibits 2 and 4, respectively.) Because the priority claim is properly made, the priority argument found in our Response dated February 28, 2001, remains fully responsive to the rejection and is renewed below.

For the reasons set forth below, this rejection respectfully is traversed.

Novak discloses a *composition* for use in preventing and treating cardiovascular disease and other disorders containing one or more phytosterols, phytostanols or mixtures of both, and one or more omega-3 polyunsaturated fatty acids (PUFA) or derivatives thereof. (Abstract). Novak discloses that:

To form phytosterol and/or phytostanol esters, one or more suitable aliphatic acids or their esters with low boiling alcohols are condensed with the phytosterol and/or phytostanol. A *wide variety* of aliphatic acids or their esters may be used successfully within the scope of the present invention and include *all aliphatic acids consisting of one or more alkyl chains with one or more terminal carboxyl groups*.

(Page 10, lines 9-13).

Novak further discloses various generic chemical structures for the aliphatic acids, e.g., R1-COOH, HOOC-R2-COOH, HOOC-R3-(COOH)₂, etc. (Page 10, line 15 to Page 11, line 14). In these structures, the respective R groups are defined in a number of different ways and include repeating units where n (the number of repeating units) is e.g., 3-25 or 1-25. (See e.g., Page 10, lines 17, 18, 23, 27, 28 and Page 11, lines 4, 10, and 14). Novak also discloses a list of 24 "preferred forms" of the aliphatic acid. (Page 11, lines 17-23).

Novak also discloses that the *composition* contains a *mixture* of the phytosterol and/or phytostanol and an omega-3 PUFA. (Page 3, lines 19-22, page 13, line 2, and claim 1).

Novak also discloses that omega-3 PUFAs "for use within the composition of the present invention are selected from alpha-linolenic acid, EPA (eicosapentaenoic acid) and DHA (docosahexaenoic acid) in the form of, *inter alia*, fatty acids, triglycerides, phospholipids, esters or free fatty acid salts." (Page 12, lines 24-27 and claims 1, and 5-7).

In making the rejection, the Examiner asserted that that "[i]t would have been *obvious ... to prepare* additional beneficial compositions by selecting specific docosahexaenoic acid and eicosahexaenoic¹ acid from fatty acid taught by prior art." (Paper 8 at 6). The Examiner acknowledged, however, that the "[i]nstant claims differ from the reference in claiming specific fatty acids *i.e.* docosahexaenoic acid and eicosahexaenoic² acid where as prior art teaches that aliphatic acid may be selected from either straight chain or branched unsaturated or saturated fatty acids." (*Id.* at 5-6).

To fill the acknowledged gap, the Examiner appears to have relied upon the alleged knowledge of one skilled in the art and the broad generic disclosure of Novak. (*Id.* at 6). The Examiner then concluded that "[t]here has been ample motivation provided by the prior art to prepare the instant invention by teaching unsaturated fatty acids and esters." (*Id.*).

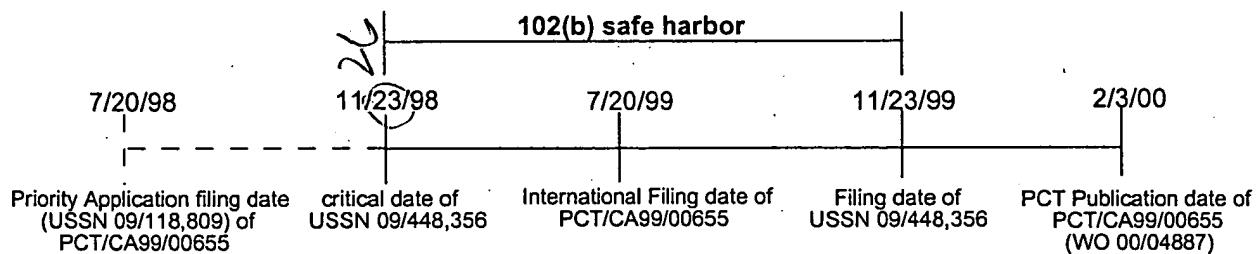
Initially, we note that once again a document relied on by the Examiner to reject the present claims in this Office Action is *not* prior art. Novak is a PCT publication that was published on "3 February 2000." See Front page line (43) International Publication Date.

¹ We note that the Examiner uses the term "eicosahexaenoic acid" when referring to one of the fatty acids recited in claim 1. Claim 1, however, recites "eicosapentaenoic acid." In this Response, we assume that the Examiner intended eicosapentaenoic acid when eicosahexaenoic acid was written. If this assumption is incorrect, the Examiner is requested to clarify this issue on the record.

Novak was filed as an International Application (PCT/CA99/00655) on 20 July 1999 (line 22) claiming priority to USSN 09/118,809 filed 20 July 1998 (line 30). (*Id.*). Accordingly, the Novak PCT publication is effective as prior art as of its *publication date, i.e., 3 February 2000*. As set forth above, the present application has an effective U.S. filing date of *November 23, 1999*.

As is well settled, whether a document is available as prior art under 35 USC §103 is determined with reference to the prior art definitions set forth in 35 USC §102. Accordingly, a review of §102 is in order with reference to Time Line-2 below.

Time Line-2



The Novak PCT publication is not prior under 35 USC §102(a) because it was neither patented (it is a PCT publication) nor published "before the invention thereof by the applicant." As Time Table-2 clearly indicates, the present application has an effective U.S. filing date of November 23, 1999, which is *prima facie* evidence of a constructive reduction to practice **prior to** the February 3, 2000 Novak PCT publication date.

The Novak PCT publication is not prior art under 35 USC §102(b) because it was not “described in a printed publication ... more than one year prior to the date of the application

² See footnote 1.

for patent in the United States." Again, the Novak PCT publication was published on February 3, 2000, whereas the critical date for the present application is November 23, 1998.

The Novak PCT publication is not prior art under 35 USC §§102(c), (d), (f), or (g) because these sections of the statute are clearly not relevant here.

The Novak PCT publication is not prior art under 35 USC §§102(e)(1) or (e)(2). §102(e)(1) is limited to (a) an application for patent published under §122 or (b) an international application *designating* the U.S. filed under the treaty defined in §351 (*i.e.*, the PCT) that was published under Article 21(2) of such treaty in the English language. Clearly, the Novak PCT publication is not an application for patent published under §122. And, an inspection of line (81) (*i.e.*, Designated States) of the front page of the Novak PCT publication indicates that the U.S. was *not* designated on the PCT Request. Accordingly, Novak is not available as prior art under §102(e)(1).

With respect to §102(e)(2), the Novak PCT publication is clearly not a *patent* granted on an application for patent by another filed in the U.S. before the invention by the applicant for patent. Because the Novak PCT publication is not a U.S. patent, it does not qualify as prior art under §102(e)(2).

For the reasons set forth above, the Novak PCT publication is not statutory prior art to the present claims. Accordingly, withdrawal of the rejection, respectfully is requested.

Claims 1, 5, 6, and 8 were rejected under 35 USC §103 as unpatentable over Miettinen. (Paper No. 8 at 7).

For the reasons set forth below, this rejection respectfully is traversed.

Miettinen is summarized above.

In making the rejection, the Examiner asserted that Miettinen teaches a composition of β -sitostanol fatty acid ester or fatty acid ester mixture and a "fatty acid mixture containing 2-22 carbon atom and esterification of sitostanol." (*Id.* at 8). The Examiner acknowledged, however, that "instant claims differ from the reference in claiming specific fatty acids *i.e.* docosahexaenoic acid and eicosahexaenoic³ acid where as prior art teaches fatty acids especially containing approximately 2-22 carbon atoms." (*Id.*).

To fill the acknowledged gap, the Examiner asserted that the "[i]nstant claims are a *selection of prior art* teachings. (*Id.* at 10).

The Examiner then concluded that "[i]t would have been *obvious ... to prepare* additional beneficial composition by selecting any fatty acids for example, docosahexaenoic acid and eicosahexaenoic⁴ acid from fatty acid 2-22 taught by the prior art." (*Id.*).

Initially, we note that claim 1, as amended recites a phytosterol ester compound produced from the reaction of phytosterol with eicosapentaenoic or docosahexaenoic acid. Further, claims 1 and 24 recite that the compound is a liquid between about -20°C and 20°C.

As is fundamental, "[t]o establish a *prima facie* case of obviousness ... the prior art reference must teach or suggest all the claimed limitations." *In re Royka*, 180 USPQ 580 (C.C.P.A. 1974); and MPEP 706.02(j), 2143, and 2143.03. Additionally, a *prima facie* case of obviousness must be based on facts. *In re Freed*, 165 USPQ 570, 571-72 (C.C.P.A. 1970). When the rejection is not supported by facts, it cannot stand. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (B.P.A.I. 1993).

³ See footnote 1.

⁴ See footnote 2.

The rejection identifies nothing in Miettinen that discloses or suggests that the compound is a liquid between about -20°C and 20°C. For this reason alone the rejection should be withdrawn.

Like the Novak rejection above, the linchpin of this rejection is the Examiner's unsupported contention that the "instant claims are a selection of prior art teachings" and that it would have been obvious to select either docosahexaenoic acid or eicosapentaenoic acid from the broad genus disclosed by Miettinen. The rejection provides insufficient evidence to support a *prima facie* case of obviousness.

We note that the rejection relies on a "selection of prior art" and "obvious to prepare" standards to reject the claims under §103. (See Paper No. 8 at 8). The statute, as well as, years of case law commands that the Examiner make the obviousness determination based on whether the "subject matter as a whole would have been obvious at the time the application was filed." (See 35 USC §103). Thus, whether or not the claimed invention is a "selection of prior art" or would have been "obvious to prepare" is irrelevant to the required analysis. *See In re Wright*, 6 USPQ2d at 1960 and 1961 (Fed. Cir. 1988) *overruled on other grounds*.

Here, not only has the Examiner applied the wrong legal standard, which, it is submitted, is reason enough for withdrawal of the rejection (see *Ex parte Levengood*, 28 USPQ2d at 1301 (B.P.A.I. 1993)), but the Examiner also has *not even alleged* that either docosahexaenoic acid or eicosapentaenoic acid fall within the scope of the genus disclosed by Miettinen. In the absence of such an allegation, the rejection has not met its burden required to support a *prima facie* case of obviousness. *See Ex parte Obukowicz*, 27 USPQ2d at 1065 (BPAI 1992). For these reasons alone the rejection should be withdrawn.

Furthermore, as we noted above, Miettinen discloses that the β -sitostanol is esterified with “*different* fatty acid ester mixtures” (Page 6, lines 28-29) that a methyl ester mixture of the fatty acids of “*any* vegetable oil can be used in the reaction” (Page 6, lines 30-32 and Page 10, lines 22-23), and that “*any* fatty acids which contain approx. 2-22 carbon atoms are usable” (Page 6, lines 33-34 and Page 10, lines 23-24). Moreover, we note that in four out of the five examples (*i.e.*, Examples 1-3 and 5) rapeseed oil was used and that Example 4 discloses the use of sunflower, soybean, olive, and corn oil as the fatty acid source. In none of these examples was an omega-3 PUFA specifically disclosed, let alone the two specific ones recited in claim 1 (*i.e.*, docosahexaenoic acid or eicosapentaenoic acid).

Thus, the rejection is silent as to how the broad generic disclosure in Miettinen would suggest either docosahexaenoic acid or eicosapentaenoic acid to one skilled in the art. The rejection is also silent as to why one skilled in the art would be motivated to try either docosahexaenoic acid or eicosapentaenoic acid given the absence of a discussion of omega-3 PUFAs in Miettinen as a source of fatty acids in the esterification process. The rejection further is silent as to how the rapeseed oil featured in four out of the five examples would, in any way, suggest either docosahexaenoic acid or eicosapentaenoic acid to one skilled in this art. This is the type of evidence required to support a rejection under §103.

Instead, the rejection relies on unsupported conclusions that the claims are “a selection of prior art” and that it “would have been obvious ... to prepare” the claimed compound using either docosahexaenoic acid or eicosapentaenoic acid. Thus, the rejection is not supported by the kind of specificity required to sustain a conclusion of obviousness. *Ex parte Humphreys*, 24 USPQ2d 1255, 1262 (BPAI 1992). (“The Examiner’s rejection is not *specific* as to *how* one

of ordinary skill in the art would have found it (the claimed invention) obvious"). For this reason also, the rejection should be withdrawn.

In sum, the rejection is insufficient as a matter of fact and law. Accordingly withdrawal of the rejection of claims 1, 5, 6, and 8 is requested.

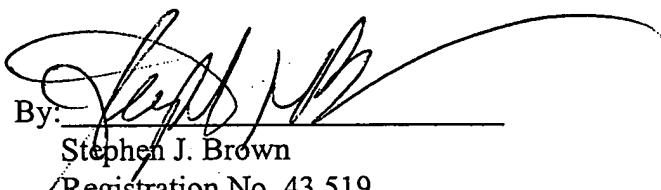
In view of the foregoing, favorable action on the merits including entry of the amendments, reconsideration and withdrawal of each of the rejections, and allowance of all the claims, respectfully, is solicited.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to the Box AF, Commissioner for Patents, Washington, DC 20231, on November 20, 2001.

Stephen J. Brown

Respectfully submitted,

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In re Application of :

U.S. Serial No.:

For:

David Carl BURDICK *et al.*

09/448,356

PHYTOSTEROL AND/OR PHYTOSTANOL DERIVATIVES

"Marked Up" Amendments to Claims Pursuant to Rule 1.121(c)

1. (Twice Amended) A phytosterol [and/or phytostanol] ester compound produced from a reaction of a phytosterol [and/or a phytostanol] with eicosapentaenoic acid or docosahexaenoic acid, said compound being liquid at temperatures from about -20°C to about 20°C.

8. (Twice Amended) A composition comprising an admixture of compounds (a) and (b) wherein [a compound according to claim 1 in admixture with a second ester of a phytosterol and/or phytostanol, wherein the second ester is the product of an esterification reaction between a phytosterol and/or phytostanol and] (a) is a phytosterol ester compound produced from a reaction of a phytosterol with eicosapentaenoic acid or docosahexaenoic acid; and (b) is a second ester which is the product of an esterification reaction between a phytosterol and/or a phytostanol and (i) a fatty acid having less than 18 or more than 22 carbon atoms and at least three carbon-carbon double bonds and/or; [(b)] (ii) a fatty acid having from 18 to 22 carbon atoms and less than three carbon-carbon double bonds.